

REMARKS

No amendments are made herewith. A complete listing of the claims is provided for the examiner's convenience.

It is respectfully submitted that the application is in condition for allowance, as described below.

Terminal Disclaimer and Double Patenting Rejection

The examiner's helpful comments regarding the terminal disclaimer are taken with appreciation. A new terminal disclaimer in accordance with the rules is submitted herewith.

The fee for the terminal disclaimer has already been paid with the previous submission, and has not been refunded. Accordingly, it is believed that no fee is due; however, the Commissioner is hereby authorized to charge Deposit Account 13-2855 under order number 29473/11372A if a fee is found to be due in connection with the terminal disclaimer.

Claim Objections

Claim 1 or 16 was objected to for informalities:

Claim 16 is objected to because of the following informalities: Claim 1 recites the limitation 'comprise' on line 3. The Examiner believes the limitation should read 'comprising'. Appropriate correction is required.

Neither claim 1 nor claim 16 recites "comprise" on the third line. To ensure that the examiner has the most current set of claims, another copy is submitted herewith. It is respectfully submitted that the objection can be withdrawn.

Claim Rejections – 35 USC § 103

Claims 1, 2, 4, 6, 7, 11-13, 16-20, and 22-26 were rejected under § 103 as obvious over Avarhami (U.S. Patent No. 6,148,232) in view of Hoffmann et al. (U.S. Patent No. 6,192,270).

Avarhami

Avarhami can be removed from consideration as a prior art reference. See MPEP 2136.05, 715.02, and 706.02(b).

Avarhami was issued on November 14, 2000, after the filing of the parent application 09/685,782 (October 10, 2000) and after the filing of the priority international application PCT/EP99/02425 (April 9, 1999). Thus, Avarhami is available as a reference only under 35 USC § 102(e), and its critical reference date is its date of filing, November 9, 1998. See MPEP 2136.03.

The requirements under 35 USC § 119 have been met, and the applicants are entitled to the priority date of the German priority application 19816143.3, April 9, 1998, which antedates the November 9, 1998, critical reference date of Avarhami. See the corrected filing receipt bearing mail date August 19, 2004.

The German priority application shows as much as the claimed invention as what is alleged to be shown in Avarhami. See MPEP 715.02, regarding the required adequacy of a showing of prior invention. A certified copy of the priority application was filed with application PCT/EP99/02425, which designated the U.S. A verified translation of the priority application is submitted herewith. Accordingly, the priority claim is perfected.

Furthermore, Avarhami describes an iontophoretic system, which is fundamentally different from the claimed invention. See, for example, column 2, lines 63-65, describing that the invention causes “a current to pass between the electrodes through the stratum corneum epidermidis, in order to generate at least one micro-channel in the stratum corneum to enable or augment transdermal movement of the substance.” As described in the previous amendment filed, the claims are structurally distinguished from references related to iontophoretic systems, wherein the current flows through the body of the patient, because in the structure of claimed invention it does not. This fundamental difference in operation is the result of fundamental differences in structure between such references cited and the claimed structure.

Thus, with respect to claim 1, the official action alleges that the embodiment of Fig. 1b in Avarhami discloses counter electrodes, citing Fig. 1b, elements 12 (¶ 10, p. 4, of the official action).

The electrodes 120 of Avarhami, however, are not counter electrodes as claimed. Rather than being counter electrodes to the electrical contacts 58 of Avarhami, the electrodes 120 themselves create an electric field between each other, creating micro-channels of electricity in the skin 22, causing the enhanced flow of active substance into the

skin (see col. 12, lines 30-44). This is an iontophoretic system. Avarhami is both structurally distinct and functionally distinct.

Similarly, with respect to independent claim 16, the official action alleges that Fig. 1b of Avarhami describes a system “wherein the carrier layer and the membrane comprise one or more electrodes such that the one or more electrodes of the membrane serve(s) as counterelectrode(s) to the one or more electrodes of the carrier layer (Fig 1b; col 12, lns 50-57” (§ 11, p. 4, of official action).

Avarhami does not disclose such a system. Instead, as described above, the embodiment described in connection with Fig. 1b creates an electrical field between the electrodes 120. The electrodes 120 do not serve as counterelectrodes to the electrical contacts 58 on the carrier layer. Lines 50-57 in column 12 of Avarhami do not support the allegation in the official action.

In view of the foregoing, the rejections under § 103/102(e) with respect to Avarhami are overcome.

Hofmann et al.

Hofmann et al. also describes an iontophoretic system, which is fundamentally different from the claimed invention. See, for example, column 2, lines 31-38, describing the operation of the device:

In accordance with the primary aspect of the present invention, molecules are brought into physical contact with the tissue surface, an electrode is contacted with the tissue surface, and an electric field is applied to the tissue surface
35 by means of the electrode. This forms pores in the tissue surface. Then a driving force is applied to the tissue surface forcing the molecules through the tissue surface into the underlying tissue.

Not surprisingly, the reference column 2, line 64, describes the process resulting from the structure of Hofmann et al. as “iontophoresis.”

In view of the foregoing, the rejections under § 103/102(e) with respect to Avarhami and Hofmann et al. are overcome.

Claims 1, 4, 12-13, 16-18, 21, 25 and 26 were rejected under § 102(e)/103(a) as obvious over Corish et al. (U.S. Patent No. 5,533,995) in view of Hoffmann et al. (U.S. Patent No. 6,192,270).

As described above, Hofmann et al. describes an iontophoretic system, which is fundamentally different from the claimed invention.

With respect to Corish et al. and independent claim 1, the official action alleges that Corish et al. discloses a system which includes a reservoir formed by a contact adhesive, citing column 3, line 52, to column 4, line 35 (§ 15 and 16, pp. 5-6 of the official action).

The cited portion of Corish et al. describing reservoir materials does not disclose a contact adhesive.

To establish *prima facie* obviousness, all of the claim limitations must be taught or suggested by the prior art, and all words in a claim must be considered in judging the patentability of the claim against the prior art. MPEP 2143.03.

If the Patent Office is alleging that one or more of the reservoir materials is inherently a contact adhesive, then a complete rejection in accordance with the rules is respectfully requested, so that the applicants can evaluate the merits of the rejection and judge the propriety of continuing the prosecution. (See 37 C.F.R. § 1.104(a)(2), "[t]he reasons for any adverse action or any objection or requirement will be stated and such information or references will be given as may be useful in aiding the applicant . . . to judge the propriety of continuing the prosecution." See also MPEP § 707 Completeness and Clarity of Examiner's Action.)

MPEP 2112 provides requirements for relying on a theory of inherency:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain

thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)

...

"In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Furthermore, an obviousness rejection cannot be based on an unknown inherent property of a prior art reference. "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is not known." *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966).

Thus, it is incumbent upon the Patent Office to substantiate the rejection based on inherency, showing that the missing descriptive matter of a reservoir formed by a contact adhesive is necessarily (not just possibly) present in Corish et al., and that it would be so recognized by persons of ordinary skill.

It is respectfully submitted that Corish et al. actually teaches against using a reservoir formed by a contact adhesive, because it teaches that other means are necessary for securing the device to the body – see col. 6, line 65, to column 7, line 6, and Fig. 1.

Similarly with respect to independent claim 16, the official action alleges that Corish et al. discloses a reservoir having a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoir, citing col. 7, lines 3-6 (§ 16, p. 6 of the official action).

Corish et al. does not disclose a reservoir having a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoir. Column 7, lines 3-6 are reproduced in full below:

More generally, the device according to the invention can be secured to the body in conventional manner such as by adhesive means, including bioadhesive means, straps, brace-

To establish *prima facie* obviousness, all of the claim limitations must be taught or suggested by the prior art, and all words in a claim must be considered in judging the patentability of the claim against the prior art. MPEP 2143.03. Corish et al. simply

suggests use of “adhesive means” for securing the device to the body. There is no teaching or suggestion to use a pressure-sensitive contact adhesive. Furthermore, there is no teaching or suggestion to use such an adhesive applied to a membrane, as presently claimed.

It is respectfully submitted that a person of ordinary skill in the art would be motivated to use an adhesive on the periphery of the housing, in a manner similar to that described in Gyory et al. U.S. Patent No. 6,083,190. See Fig. 1, element 28. The person of ordinary skill in the art would interpret the disclosed use of adhesive as suitable for use on the housing because it is functionally similar to the use of strap or bracelet -- it secures the entire device to the body. In addition, the person of ordinary skill in the art would not place an intervening layer of adhesive between the membrane and the body, due to the unknown and likely detrimental consequences for drug transport, as described below.

To establish a *prima facie* case of obviousness, not only must there be some motivation to modify the reference but also a reasonable expectation of success found in the prior art, and not based on the applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §§ 2142-2143.

The Patent Office has not shown that the prior art would provide the requisite expectation of success in modifying Corish et al. with an adhesive applied to a membrane, as presently claimed. To the contrary, Corish et al. itself discloses that in such a device, use of its disclosed intervening “transit chamber” 15 retards transport of active agent. See column 10, lines 57-61 and column 12, lines 4-9.

The prior art does not provide an expectation that disposing an intervening adhesive between membrane and skin in the apparatus of Corish et al. would not retard transport of active agent and frustrate operation of the device. If a transit chamber, which is specifically designed to hold active agent, retards transport, then the use of an adhesive would not be expected to be any different, and likely would be viewed with more skepticism.

Claims 1, 2, 4, 6, 7, 11-14, and 16-27 were rejected on the ground of non-statutory obviousness-type double patenting. The rejections can be withdrawn in view of the terminal disclaimer submitted herewith.

CONCLUSION

In view of the foregoing, withdrawal of the rejections and allowance of all pending claims are respectfully requested. Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to telephone the undersigned attorney at the indicated number.

Respectfully submitted,
MARSHALL, GERSTEIN & BORUN LLP

By: /Michael Muczynski #48,642/
Michael Muczynski
Reg. No. 48,642
Attorney for Applicants

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6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606
(312) 474-6300